DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

DIAZYME LABORATORIES
DR. ABHIJIT DATTA
12889 GREGG COURT
POWAY CA 92064

August 6, 2014

Re: K133803
Trade/Device Name: Diazyme Glycated Serum Protein POC Test Kit
Regulation Number: 21 CFR 864.7470
Regulation Name: Glycosylated hemoglobin assay
Regulatory Class: II
Product Code: LCP
Dated: July 9, 2014
Received: July 10, 2014

Dear Dr. Datta:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Katherine Serrano -S

For: Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
k133803

Device Name
Diazyme Glycated Serum Protein POC Test Kit

Indications for Use *(Describe)*
The Diazyme Glycated Serum Protein POC Test Kit is intended for the quantitative determination of glycated serum proteins (GSP; fructosamine) in serum. Fructosamine is representative of blood glucose levels over the course of 2-3 weeks. The measurement of glycated serum proteins is useful for monitoring diabetic patients. For in vitro diagnostic use only.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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510(k) SUMMARY & SUBSTANTIAL EQUIVALENCE COMPARISON

Summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

Submitter's name:	Diazyme Laboratories
Submitter's address:	12889 Gregg Court Poway, CA 92064 USA
Name of Contact Person:	Dr. Abhijit Datta Diazyme Laboratories 12889 Gregg Court Poway, CA 92064 Phone: 858-455-4762 Fax: 858-455-2120 abhijit.datta@diazyme.com
Date the Summary was Prepared	July 9, 2014
Name of Device	Diazyme Glycated Serum Protein POC Test Kit
Trade Name	Diazyme GSP POC Test Kit
Common/Usual Name	Diazyme GSP POC Test Kit
Device Classification Name	Assay, Glycosylated Hemoglobin
Product Code	LCP
Panel	Clinical Chemistry
Submission Type	Traditional 510k
Regulation Number	864.7470 – Glycosylated hemoglobin assay
Device Class	Class II

Predicate Device	Diazyme Glycated Serum Protein (GSP) Assay (k110188) Diazyme Glycated Serum Protein Calibrator Kit (k110188) Diazyme Glycated Serum Protein Control Kit (k110188)
Manufacturing Address	Diazyme Laboratories 12889 Gregg Court Poway, CA 92121 USA
Establishment Registration	2032900

Executive Summary

Detailed performance characteristics and comparison analysis are given in this filing that demonstrates substantial equivalence of the GSP POC Assay Kit to predicate device that is currently being marketed. The performance characteristics of the GSP POC Assay Kit are substantially similar to that of the approved predicate device (k110188). Performance data and risk analysis indicates that differences should not affect the safety and effectiveness of the GSP POC Assay and offers POL users an *in vitro* diagnostic device system to measure GSP in human serum samples.

Device Description:

Clinical Significance

Fructosamine is formed due to a non-enzymatic Maillard reaction between glucose and amino acid residues of serum proteins. It is reported in medical literature that 80% of measured glycated serum proteins are glycated albumins. In diabetic patients, elevated blood glucose levels correlate with increased fructosamine formation. Glycated serum proteins (GSP; fructosamine) are a medium term indicator of diabetic control (2-3 weeks).

Assay Principle

The Diazyme Glycated Serum Protein POC Assay uses proteinase K to digest GSP into low molecular weight glycated protein fragments (GPF), and uses Diazyme's specific fructosamiase^{TM}, a microorganisms originated amadoriase to catalyze the oxidative degradation of Amadori product GPF to yield peptide fragments (PF) or amino acids, glucosone and H_2O_2. The H_2O_2 released is measured by a colorimetric Trinder end-point reaction. The absorbance at 546 nm is proportional to the concentration of glycated serum proteins. The SMART analyzer calculates the GSP concentrations of patient serum specimens by use of a lot specific calibration curve. The lot specific curve is represented in a Calibration card (RFID) provided with each GSP POC Test Kit.

SMART Analyzer (K092911) is a compact cuvette based spectrophotometer (10 inches x 5.5 inches x 5.5 inches) machine for point-of-care testing designed to analyze readings from single use reagent cuvette. The instrument only uses the Diazyme Reagent System (DRS) cuvette and caps and performs assay with a preprogrammed Radio Frequency ID (RFID) card. The DRS cuvette is supplied prefilled with Reagent 1 (R1) and the DRS cap is supplied prefilled with Reagent 2 (R2). The DRS cuvette and caps are kept separate until use. Users are instructed (see proposed labeling) to add 40µl of sample to the DRS cuvette prefilled with R1 containing proper buffer. Users are then instructed to snap in place DRS cap and insert into analyzer. The instrument warms the cuvette to 37^{o}C and after a predefined period adds the reagent R2 found in the DRS cap. The reagents and samples are mixed magnetically and absorbance readings are taken at 546nm. The lot specific RFID card contains reagent addition time, mixing time, reading time and lot specific calibration curve.

The Diazyme GSP POC Test Kit system thus consists of the following:

- GSP POC Test Kit. Reagents are provided in prefilled tubes, cuvettes and cuvette caps. The DRS cuvette and cuvette caps can only work with the SMART analyzer.

Indications for Use

The Diazyme Glycated Serum Protein POC Test Kit is intended for the quantitative determination of glycated serum proteins (GSP; fructosamine) in serum. Fructosamine is representative of blood glucose levels over the course of 2-3 weeks. The measurement of glycated serum proteins is useful for monitoring diabetic patients. For in vitro diagnostic use only.

Indications for Use

Predicate k110188	Candidate device	Equivalency
Diazyme Glycated Serum Protein Assay Kit in conjunction with Diazyme Glycated Serum Protein single calibrator, are intended for the quantitative determination of glycated serum proteins (GSP; glycated albumins; fructosamine) in serum. The measurement of glycated serum proteins is useful for monitoring diabetic patients	The Diazyme Glycated Serum Protein POC Test Kit is intended for the quantitative determination of glycated serum proteins (GSP; fructosamine) in serum. Fructosamine is representative of blood glucose levels over the course of 2-3 weeks. The measurement of glycated serum proteins is useful for monitoring diabetic patients. For in vitro diagnostic use only.	Similar

Principle

Predicate k110188	Candidate device	Equivalency
The Diazyme Glycated Serum Protein Assay uses Proteinase K to digest Glycated Serum Proteins (GSP) into low molecular weight glycated protein fragments (GPF), and uses Diazyme's specific fructosaminaseTM, a microorganism originated amadoriase to catalyze the oxidative degradation of Amadori product GPF to yield PF or amino acids, glucosone and H2O2. The H2O2 released is measured by a colorimetric Trinder end-point reaction. The absorbance at 600 nm is proportional to the concentration of glycated serum proteins.	The Diazyme Glycated Serum Protein POC Assay uses proteinase K to digest GSP into low molecular weight glycated protein fragments (GPF), and uses Diazyme's specific fructosaminaseTM, a microorganisms originated amadoriase to catalyze the oxidative degradation of Amadori product GPF to yield peptide fragments (PF) or amino acids, glucosone and H2O2. The H2O2 released is measured by a colorimetric Trinder end-point reaction. The absorbance at 546 nm is proportional to the concentration of glycated serum proteins. The SMART analyzer calculates the GSP concentrations of patient serum specimens by use of a lot specific calibration curve. The lot specific curve is represented in a Calibration card (RFID) provided with each GSP POC Test Kit.	Similar

Test Objective

Predicate k110188	Candidate device	Equivalency
For the *in vitro* quantitative determination of glycated serum proteins (GSP; glycated albumins; fructosamine) in human serum.	For the in vitro quantitative determination of glycated serum proteins (GSP; glycated albumins; fructosamine) in human serum.	Same

Type of Test

Predicate k110188	Candidate device	Equivalency
Quantitative	Quantitative	Same

Methodology

Predicate k110188	Candidate device	Equivalency
Enzymatic method	Enzymatic method	Same

Specimen

Predicate k110188	Candidate device	Equivalency
Human serum	Human serum	Same

Product Type

Predicate k110188	Candidate device	Equivalency
2 Reagents Liquid (ready-to-use)	Prefilled ready to use DRS Cuvettes, lot specific RFID calibration card	Similar

Performance

Predicate k110188	Candidate device
Linear Range: up to 1354 µmol/L Precision: Within: < 2.0 % CV Total: < 2.0 % CV Method comparison with predicate: Correlation Coefficient: 0.9966 Slope/Intercept: 0.9542/14.57	Linear Range: 61 to 1348 µmol/L Within precision ≤ 5.6 % CV Total Precision: ≤ 6.1 % CV Accuracy: Correlation Coefficient: 0.99 Slope/Intercept: y = 0.97/ 0.69

Calibrator Comparison

Predicate k110188	Candidate device	Equivalency
Separately packaged calibrator kit. User steps needed to use calibrators. The instrument calculates the GSP concentration of a patient specimen by interpolation of the obtained signal on a 2 point calibration curve	Each kit has individual lot specific RFID preprogrammed calibration card. User steps limited to insertion in SMART analyzer. The instrument calculates the GSP concentration of a patient specimen by use of a lot specific calibration curve that is stored in an RFID card provided with each GSP POC kit.	Similar

Control Comparison

Control material is the same as predicate device k110188

Summary of Assay Kit Components

Predicate k110188	Candidate device
Kit can be used on automated chemistry analyzers using validated parameters	Kit can ONLY be used with SMART analyzers
Reagent 1 1 bottle • Enzyme/substrate reagent containing Good's Buffer, 4-AA, enzymes, and stabilizers	Reagent 1 40 DRS cuvette (prefilled) with reagent R1 • Enzyme/substrate reagent containing Tris.HCl buffer, 4-AA, Enzymes and stabilizers
Reagent 2 1 bottle • Enzyme/substrate reagent containing Good's Buffer, enzymes, TOOS, HRP, Geneticin, and stabilizers	Reagent 2 40 DRS caps (prefilled) • Enzyme/substrate reagent containing Tris.HCl buffer, enzymes, TOOS, HRP, Geneticin, and stabilizers
Calibrator set	Calibrator
2 x 1.0 mL Calibrator 1 and 2	1 x preprogrammed lot specific RFID card in each kit
Control Set	Control Set (same as predicate k110188)
1 x 1.0 mL Control 1(buffer based liquid, ready to use)	1 x 1.0 mL Control 1(buffer based liquid, ready to use)
1 x 1.0 mL Control 2(buffer based liquid, ready to use)	1 x 1.0 mL Control 2 (buffer based liquid, ready to use)

Equipment needed for Diazyme GSP POC Test Kit:

- SMART Analyzer (K092911).

Special conditions for use statement(s):

- For prescription use only

Special instrument requirements:

- For use on SMART Analyzer only

Performance Characteristics:

Precision Study

The precision of the Diazyme GSP Assay was evaluated according to CLSI EP5-A guideline. In the study, 5 serum samples containing about 87, 226, 479, 743, and 1243 µmol/L fructosamine, respectively, were tested 2 runs per day in duplicates over 20 working days.

The mean value (Mean), standard deviation, within-run imprecision and total imprecision are calculated and summarized in the following tables:

Specimen	*n*	Mean (mg/L)	Within Run SD (mg/L)	Within Run CV (%)	Total SD (mg/L)	Total CV (%)
Serum Level 1	80	87	5.26	6.1%	4.8	5.6%
Serum Level 2	80	226	9.75	4.3%	10.14	4.5%
Serum Level 3	80	479	16.10	3.4%	16.48	3.4%
Serum Level 4	80	743	12.12	1.6%	18.81	2.5%
Serum Level 5	80	1243	18.60	1.5%	22.71	1.8%

LOB/LOD/LOQ

LOB = 12 µmol/L; The LOD = 30 µmol/L and LOQ = 61µmol/L

Linearity/assay reportable range:

Twelve levels of linearity set were prepared by diluting a sample containing 1348 µmol/L Fructosamine with low sample with 2 µmol/L Fructosamine according to CLSI EP6-A and analyzed on SMART Analyzer. Results indicated linearity from 2 to 1348 µmol/L. Allowable systematic error (SEA) was 4.9%.

Interference:

The common interfering substances had no significant interference up to the concentrations summarized below.

Interference	Concentration
Ascorbic Acid	20 mg/dL
Bilirubin	7.5 mg/dL
Bilirubin Conjugated	5 mg/dL
Triglyceride	1000 mg/dL
Glucose	2400 mg/dL
Uric Acid	35 mg/dL

Hemoglobin	100 mg/dL
Total Protein	12 mg/dL

Comparison studies:

A total of forty nine serum specimens were tested with Diazyme GSP POC Test on SMART analyzer. The correspondent plasma samples were tested with Diazyme GSP Assay on Hitachi 917 analyzer (predicate k110188).

The regression results are summarized in the following table:

	Results
n	54
Slope	0.9737 (95%CI:0.95599-0.9944)
Intercept (μmol/L)	0.6859 (95% CI: -4.7287-7.8918)
Correlation coefficient, r	0.9975 (95%CI:0.9956-0.9985)
Range of values (μmol/L)	70.0 to 1269

Expected value/Reference range

Previously established for predicate device (k110188)

Adults (>18 years) have a reported normal range of 191-289 μmol/L. It is recommended that each laboratory establish its own reference range to reflect the age, sex, diet and geographical location of the population.